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09/974,882	10/10/2001	Edward M. Nolan	GENE1320-2	8790

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EXAMINER

SULLIVAN, DANIEL M.

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

09/974.882

NOLAN ET AL.

Office Action Summary

Examiner

Art Unit

Daniel M Sullivan

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) - in no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 21 and 24 is/are rejected.
- 7) ☐ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 14 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is a response to the "Response to Office Action" filed 14 January 2003 (Paper No. 11) in reply to the Non-Final Office Action mailed 19 October 2002 (Paper No. 8). Claims 21, 24 and 25 were considered and claims 1-20 and 23 were withdrawn from consideration in Paper No. 8. Claims 21 and 25 were amended in Paper No. 11. Claims 1-21 and 23-25 are pending in the application. Claims 21, 24 and 25 are under consideration herein.

Election/Restrictions

This application contains claims 1-20 and 23 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Oath/Declaration

Applicant states that a new Declaration which corrects the defect identified in the previous office action has been submitted with the response. However, no substitute Declaration accompanied the response and the transmittal sheet does not indicate that a substitute Declaration was filed with the amendment. Therefore, the requirement for a new Declaration stands.

Drawings

The formal drawings submitted 14 January 2003 are approved.

Response to Amendment

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Claim Rejections - 35 USC § 112

Rejection of claim 25 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn.

Claim Rejections - 35 USC § 102

Rejection of claims 21 and 24 under 35 U.S.C. 102(b) as anticipated by Jaroszeski *et al.* (1994) *Anal. Biochem.* 216:271-275 is withdrawn in view of Applicant's arguments of record in Paper No. 11.

Claim Rejections - 35 USC § 103

Claims 21 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Strauss and Jaenisch (1992) 11:417-422 in view of Chernomordik *et al.* (1991) *Biochim Biophys. Acta* 1070:193-197 for reasons of record in Paper No. 8 and herein below in the "Response to Arguments".

It is noted that the first sentence of the claim rejection in the previous office action indicated that claims 23 and 24 were rejected. This was an obvious typographical error as evidenced by the fact that the Office Action clearly indicated that claim 23 was not under consideration therein, claim 24 depends from claim 21 and the grounds for rejection set forth in the body of the claim clearly address the limitations of the method of claim 21 and not the apparatus of claim 23. Therefore, it was clear that the rejection was made against claims 21 and 24, not claims 23 and 24. It is also noted that Applicant's arguments in response to the rejection are directed to the limitations of claim 21, not claim 23.

Response to Arguments

Claim Rejections - 35 USC § 103

In response to the rejection of claims 21 and 24 under 35 U.S.C. 103(a) as unpatentable over Strauss and Jaenisch in view of Chernomordik *et al.*, Applicant argues that Strauss and Jaenisch neither teach nor suggest that an electroporating electric field could be used to improve the efficiency of chromosome transfer into cells and Chernomordik fails to overcome this deficiency. Applicant argues that, in view of teachings from Strauss and Jaenisch indicating fragility of YAC DNA and the teaching from Chernomordik that the percentage of dead cells increases with the intensity of the electric field, the skilled artisan would not have a reasonable expectation of success in combining the references because one of ordinary skill might as well expect that the electric pulses applied to the cells/liposome mixture would damage the chromosomes. This argument has been fully considered but is not found persuasive. Applicant is reminded that the standard for obviousness is a reasonable expectation of success. Although Strauss and Jaenisch teach that YAC DNA is unstable in the absence of spermine, the addition of spermine does, in fact, stabilize the DNA. As there is no reason to expect that the DNA in the presence of spermine would be any less stable in the presence of an electric field, the skilled artisan would have a reasonable expectation of success in introducing the encapsulated YAC DNA by a method that comprises electroporation as taught by Chernomordik. With regard to Chernomordik's teaching that the percentage of dead cells increases with electric field intensity, there is nothing in Chernomordik's teaching to indicate that the cell death is due to chromosome damage. In fact, because cell death was determined within 40 minutes of electroporation, it is

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unlikely that cell death was the result of chromosome damage. Furthermore, the skilled artisan would know to titrate the intensity of the electrical pulse in order to optimize introduction of the chromosomes.

Finally, Applicant argues that Chernomordik fails to disclose that electric field treatment of the liposome encapsulated fluorescent dye and cells results in the cells being "transformed" with the dye molecules, and there is no suggestion by Chernomordik that the dye molecules are actually transferred from the liposomes to the interior of the cells. These arguments are not persuasive because, clearly, the reason that Chernomordik fails to achieve transformation using the dye molecules is because the dye molecules do not comprise DNA, which is taught by Strauss and Jaenisch. Also, Applicant concedes that Chernomordik teaches increased binding of intact liposomes onto the cell membranes. Given that binding to the cell membrane is the first step in internalization of any molecule, it would be reasonable to expect that any treatment producing an increase in binding of a molecule to the plasma membrane would also increase internalization of that molecule. Therefore, the claims stand rejected as unpatentable over the teachings of Strauss and Jaenisch in view of Chernomordik *et al.*

Allowable Subject Matter

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

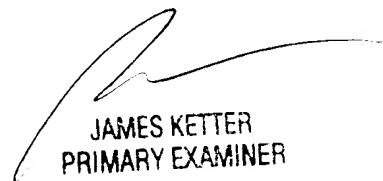
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
March 13, 2003


JAMES KETTER
PRIMARY EXAMINER